



**Improving Patient Safety and Supply Chain  
Efficiency with Data Standards:  
*The Basics of GS1 Standards in Healthcare***

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Director Supply Chain, USC Health Sciences

Past President, AHRMM

GS1 Healthcare US Leadership Team

**November 9, 2009**

# Introduction to GS1 Healthcare US

-  **Who is GS1®?**
-  **Who is GS1 US™?**
-  **GS1 Healthcare – Global Standards**
-  **GS1 Healthcare US™ – Standards Implementation**





# Who is GS1?

**GS1** is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **108** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

**GS1 is the most widely used supply chain standards system in the world**



## Who is GS1 US ?

### Formerly Known as the UCC

- Established **1973** (*think U.P.C.*)

### Implements the **GS1 System** in the U.S.

- **23** industries, **200,000** members in U.S.
- **1 million** global members, **150** Countries
- **16,000** identified healthcare members in U.S.
- Uniquely identify products, assets, and locations
- Bar codes, EPC, e-Commerce, UNSPSC®

### **Voluntary, Not-for-Profit, Neutral, Member Driven**



# GS1 Standards in Healthcare

## Five Patient Rights

Right Patient  
Right Drug/Device  
Right Time  
Right Dose  
Right Route

### Enable traceability and authentication systems

- Fight counterfeiting
- Effective & efficient product recalls
- Improve supply chain efficiency

### Enable AIDC systems all the way to the point-of-care or point-of-sale

- Ensure the 5 patient rights
- Reduce medication errors
- Improve supply chain efficiency

### Enable regulatory compliance

- Pedigree legislation in California, etc.



# GS1 Healthcare

GS1 Healthcare is a **voluntary**, global user community bringing together all healthcare stakeholders.

**Manufacturers ♦ Wholesalers ♦ Distributors Hospitals ♦ Pharmacies ♦ Regulatory Bodies ♦ Trade Associations ♦ GS1 Member Organisations**

## *2009 Leadership Team*



Mike Wallace



Grant Hodgkins



Volker Zeinar



Frédérique Fremont



Co-Chair: Mark Hoyle



Ramesh Murthy



James Hickland



Tom Werthwine



Ron Bone



Jackie Elkin



Scott Cameron



Co-Chair: Tim Marsh



Joe Pleasant



Jim Willmott



in Europe



US



Japan



# Local Healthcare User Groups Who Are Driving Adoption



France



Canada



Austria



Russia



US



UK



Malta



Australia



Mexico



Serbia & Montenegro



Belgium & Luxembourg



New Zealand



Switzerland



Algeria



Spain



Japan



Morocco



Tunisia



Netherlands



Denmark



Germany



Macedonia



Sweden



Slovakia

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A large, light gray outline of the United States map serves as a background. Inside the map, the top left corner is filled with a blue field containing white stars, and the rest of the map is filled with horizontal red and white stripes, mimicking the US flag.

# **GS1 Healthcare US - Standards Implementation**





# 110 Member Companies

## Industry Associations (17)

- AAP - American Academy of Pediatrics
- AHA - American Hospital Association
- AHRMM - Association for Healthcare Resource and Materials Management
- ASHP - American Society of Health-System Pharmacists
- CHPSO - California Hospital Patient Safety Organization
- CHSCR - Center for Healthcare Supply Chain Research
- Dental Trade Alliance
- GHVRHIO - Greater Hudson Valley Regional Health Information Organization
- GPhA - Generic Pharmaceutical Association
- HDMA - Healthcare Distribution Management Association
- HIDA - Health Industry Distributors Association
- Medical Device Supply Chain Council
- MITA - Medical Imaging & Technology Alliance
- NACDS - National Association of Chain Drug Stores
- NCPD - National Coalition of Pharmaceutical Distributors
- NCPDP - National Council for Prescription Drug Programs
- SMI - Strategic Marketplace Initiative

## Manufacturers (21)

- Abbott Laboratories, Inc.
- Baxter International, Inc.
- Becton Dickinson
- Boehringer Ingelheim USA
- Bristol-Myers Squibb Company
- Covidien
- C.R. Bard
- GE Healthcare
- Genzyme Corporation
- GlaxoSmithKline
- Johnson & Johnson
- Kimberly-Clark Corporation
- Medical Action Industries
- Medline
- Medtronic, Inc.
- Merck & Company, Inc.
- Novartis Pharmaceuticals Corporation
- Pfizer, Inc.
- Sage Products, Inc.
- Stryker
- Talecris Biotherapeutics, Inc.



# 110 Member Companies

## Solution Providers (25)

- Accenture
- Acsis, Inc.
- AXWAY
- BravoSolutions
- Clarkston Consulting
- Craneware, Inc.
- D2 Pharma Consulting LLC
- DataPros for Healthcare
- Deloitte Consulting
- ECRI Institute
- GHX
- Lansa, Inc.
- Lawson Software
- Loftware, Inc.
- MediClick, Inc.
- Noblis
- Optel Vision
- PharmTech, Inc.
- Product Identification & Processing Systems, Inc.
- rfXcel Corporation
- SAP AG
- Systech International
- Tecsys, Inc.
- TraceLink, Inc.
- Vendormate, Inc.

## Retailers (1)

- CVS Pharmacy

## Distributors (4)

- AmerisourceBergen Drug Corporation
- Cardinal Health
- McKesson
- Owens & Minor

## Academic Institutions (2)

- CIHL - Center for Innovation on Healthcare Logistics
- Wright State Research Institute

## Government Agencies (4)

- DMSB - Defense Medical Standardization Board
- DoD/DMLSS - Defense Medical Logistics Standard Support
- Dept. of Veteran Affairs
- FDA - US Food and Drug Administration

## Group Purchasing Organizations (7)

- Amerinet
- Consorta
- GNYHA Services
- HealthTrust Purchasing Group
- MedAssets
- Novation LLC
- Premier, Inc.

## Hospitals/IDNs (29)

- Ascension Health
- Atlantic Health
- BJC Healthcare
- Carolinas Healthcare System
- Catholic Health Initiatives
- Geisinger Health System
- Intermountain Healthcare
- Johns Hopkins Health Systems
- Kettering Health Network
- Louisiana State University Health Sciences Center
- Mayo Clinic
- Ministry Health Care Inc.
- Munroe Regional Medical Center
- New York Presbyterian Hospital
- OSF Healthcare System
- PeaceHealth
- Premier Health Partners
- Ridgeview Medical Center
- Sentara Healthcare
- Sisters of Mercy ROI
- SSM Healthcare
- Surgical Care Affiliates
- The Ohio State University Medical Center
- UK Healthcare
- University of Mississippi Medical Center
- University of Virginia Medical Center
- University of Wisconsin Medical Foundation
- University Southern California Health Sciences
- Wellspan Health

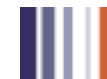
# GS1 Healthcare US Leadership Team

Healthcare Category*	Term ends 12/31/09	Term ends 12/31/10
Acute Care Provider	Joe Dudas Mayo Clinic	Jean Sargent USC Health Sciences
Alternate Site Provider	Vacant	Mary Ann Michalski Surgical Care Affiliates
Distributor	Ron Bone McKesson	Bill Zimmerman Cardinal Health
GPO	Mary Beth Lang Amerinet	Dennis Byer Novation
Healthcare Assns, Education, Government, Solution Providers**	Debbie Sprindzunas AHRMM	Dennis Orthman SMI
Medical Device Manufacturer	Dennis Black Becton Dickinson	Roy Ludvigsen Kimberly-Clark Corp
Pharmaceutical Manufacturer	Mike Rose Johnson & Johnson	Peggy Staver Pfizer, Inc
Retail Pharmacy	Vacant	Ramesh Murthy CVS Pharmacy
<b>Ex-Officio Guests (non-voting)***</b>	Steve Perlowski NACDS	Perry Fri HDMA

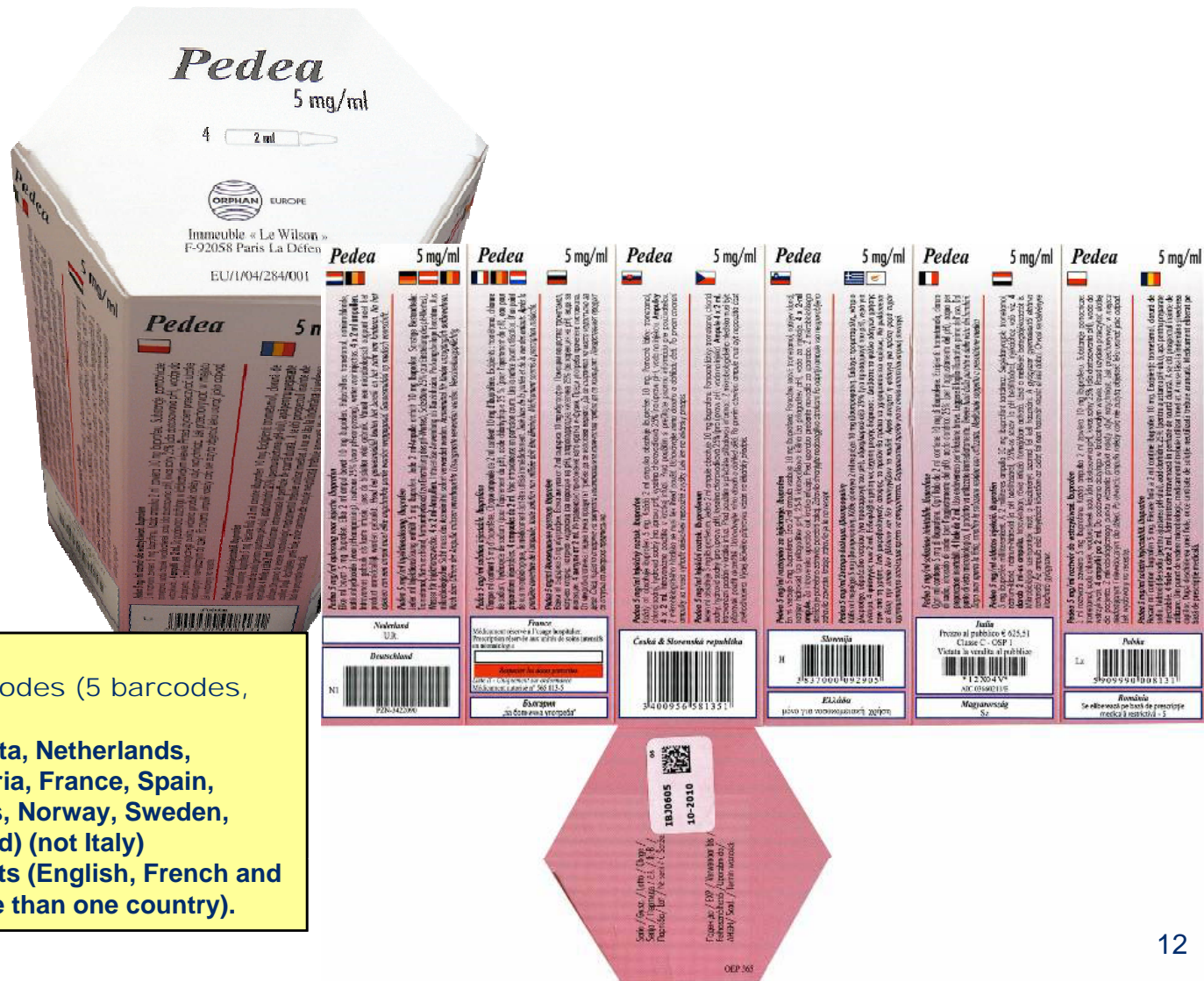
*\*Two representatives allowed for each category: (1) one-year term & (1) two-year term*

*\*\*Non voting members*

*\*\*\*Through December 31, 2009*



# Why Global Standards?



## The package has:

- 6 machine readable codes (5 barcodes, 1 Data Matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).

# Same Product – Different Numbers\*

## ■ Industry Distributor Numbers for 3M Product # 8630:

Allegiance	- M8630
Owens & Minor-	4509008630
BBMC-Colonial-	045098630
BBMC-Durr	- 081048
Kreislers	- MINN8630
Midwest	- TM-8630
Pacific	- 3/M8630
UnitedUMS	- 001880

*Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.*



\* Source: Department of Defense Data Synchronization Study



# Same Number Different Products\*

*Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.*

■ Part Number: 10313  
refers to:

**Medtronic's** - "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"

**Hantover's** - "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"

**Chattanooga Group's** - "ACCESSORY TRACTION REPLACEMENT STRAP XL FOR HALTER THORACIC RESTRAINT"

**HF Scientific's** - "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

■ Part Number: 1050 refers to:

**3M Company's** - "DRAPE INCISE 35 3/8X 17 5/8IN"

**Tyco's** - "PAD TELFA 3 X 4IN STER"

\* Source: Premier Inc. Product Item Master

# What is the pain?

Too many identifiers for the same healthcare location  
= Confusion, finger pointing, & inefficiency

SAINT JOHN'S QUEENS HOSPITAL  
1100004570208

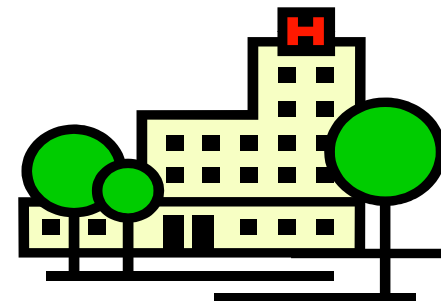
ST JOHN'S QUEENS HOSPITAL  
100084547

SAINT JOHNS QUEENS HOSPITAL  
JAOE

SAINT JOHN'S QUEEN HOSPITAL  
50003000431

SAINT JOHN'S QUEEN'S HOSPITAL  
CA2053

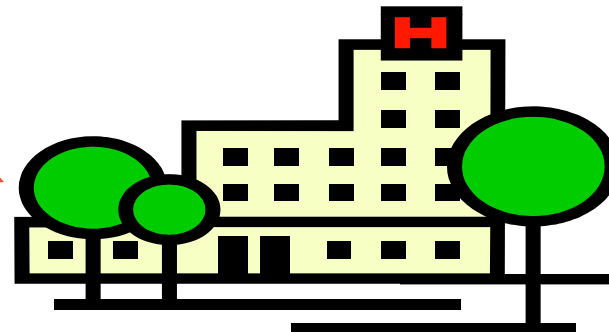
ST. JOHN'S QUEENS HOSPITAL  
OM 12345



Many different names  
and location numbers  
for 1 hospital

# GLN Registry for Healthcare®

SAINT JOHN'S  
QUEENS HOSPITAL  
1100004570208



**One standard locator GLN with  
address rationalized through  
US Postal Service**





# The GS1 System

## 3G's and U:

GTIN	Product Identification
GLN	Location Identification
GDSN	Data Attribute Accuracy
<u><i>and</i></u>	
"UNSPSC®"	Product Classification



# Provider Tool Kits: GTIN, GLN, GDSN, UNSPSC

Introduction to the Standards

Implementation Steps

Lessons Learned

Benefits to Healthcare Providers

ROI Hot Spots

FAQs

[www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit)



# **New! Supplier Tool Kits: GTIN, GLN, GDSN**

Introduction to the Standards  
Implementation Steps  
Lessons Learned  
Benefits to Healthcare Providers  
ROI Hot Spots  
FAQs  
[www.gs1us.org/hcsuptoolkit](http://www.gs1us.org/hcsuptoolkit)



# What is a GTIN<sup>®</sup>?

GTIN is Global Trade Item Number

A globally unique 8, 12, 13, or 14-digit number that uniquely identifies products and services

An identification number of the GS1 System, therefore unique and unambiguous

A global standard for collaborative commerce

A 14-digit GTIN is encoded in a GS1-128/DataMatrix /Databar

GS1 -128 (14-digit GTIN)



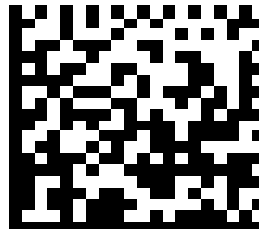
DataMatrix (14-digit GTIN)



Databar (14-digit GTIN)



# GTIN: Healthcare Example



(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

GTIN (Global Trade Item Number)

Expiry Date

Lot Number

Serial Number



# Traceability Ladder of Precision

## GTIN and Serial Number identifies a precise product and packaging size

- 1 0300710362403 (21) 123456asd
- Dilantin Blister
- Serial Number 123456asd

## GTIN and Lot Number identifies Products within a defined group

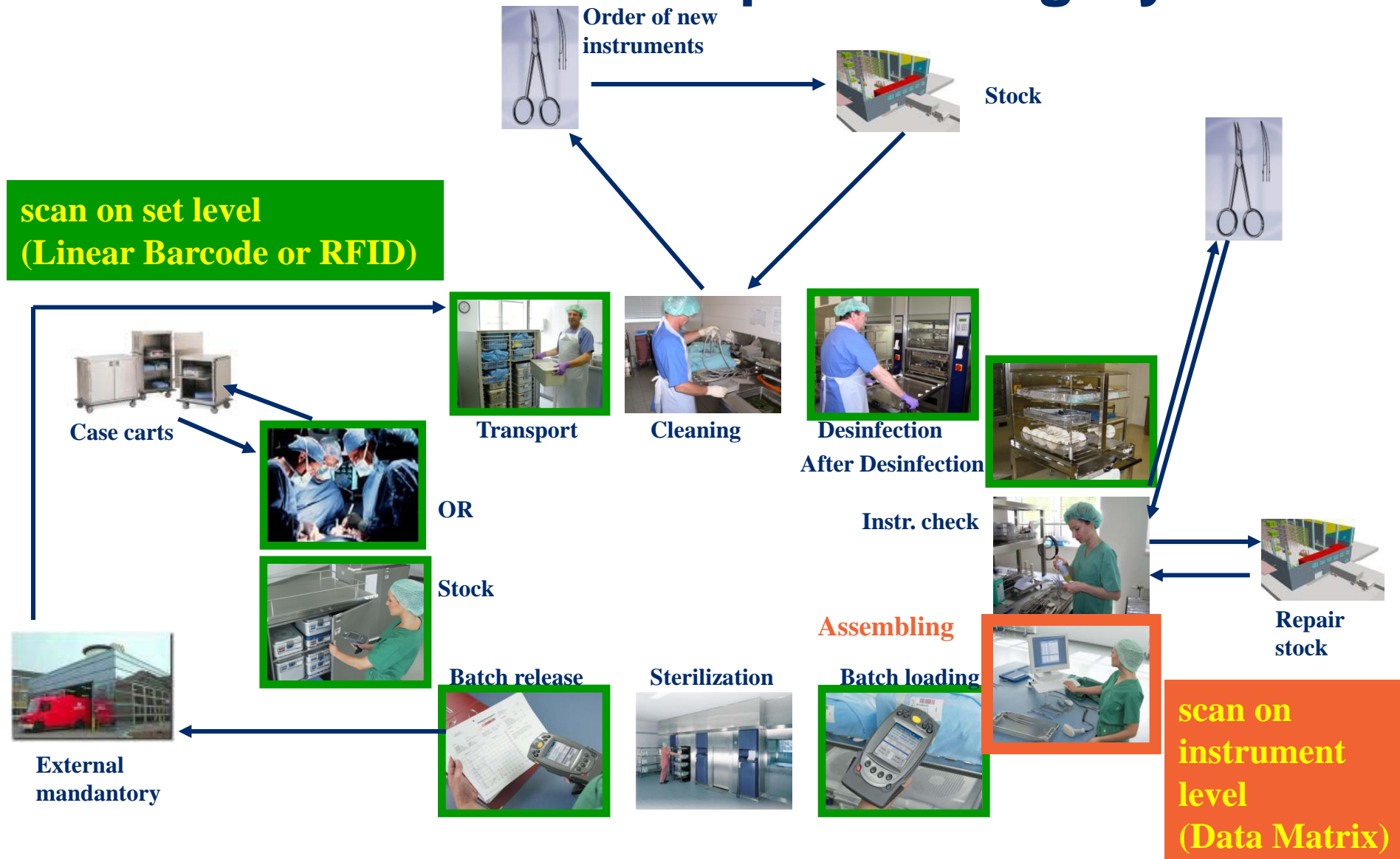
- 1 0300710362403 (10) 05724f
- Dilantin Blister
- Lot number 05724F

## GTIN identifies product and package

- 1 0300710362403
- Dilantin Blister



# Micro Logistic means: Instrument Reprocessing Cycle



# 2012 GTIN Sunrise



## “Adoption of GTIN in Healthcare by 2012\*”

Global Trade Item Numbers (GTINs)\*\*

- GTINs are assigned to healthcare products
- GTINs are used in business transactions
- GTINs are marked on appropriate packaging levels
- GTINs are scanned at points-of-delivery to enhance clinical process
- GTINs are used in product returns and recalls
- GTINs are registered in a GS1 GDSN-certified Data Pool

**\*December 2012**

**\*\*Unique Product Identifiers**







# 2012 GTIN Sunrise

## “Adoption of GTIN in healthcare by 2012”

		Phase One Awareness	Phase Two Notify Trading Partners	Phase Three Contract & Systems	Phase Four Transaction	Phase Five 2012 Implementation
Provider & Distributor Suppliers Software Providers	Provider & GPO	Know GS1 System Standards. Review internally what must be changed to accept.	Notify trading partners of need for GTIN, and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number) and ask their ability to meet it.	Terms and condition of contracts specify applicable GS1 Standards, specifically GTINs. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards.
	Distributor	Know GS1 System Standards. Review incoming material and the ability of internal systems to accept.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	Terms and conditions of contracts specify applicable GS1 Standards on products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered, received and shipped are marked in accordance with GS1 Standards.
	Suppliers	Know of impending requirement, access ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	Terms and conditions of contracts call for GS1 Standards on all products: GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards and have the minimum number of data attributes loaded into a shared data catalog (e.g. GDSN).
	Software Providers	Know of impending requirement, access ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	GS1 Standards are imbedded in all products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority if not all transactions and software has been developed to support.	All products have specific segments identified for GS1 Standards, following allocation rules in the specifications.

# FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

- The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.



## Medical Device Adverse Events

For 2007, we received ~ +100k reports  
~ 15% lacked model or catalogue number  
~ 50% lacked lot or other identifier  
~ 10% lacked both

The face of things to come...

(01)00802526255410(17)080531(10)6062151

## Medical Device Recalls (2007)

- 41 Class I recalls
- 931 Class II recalls
- 78 Class III recalls
- Class I – 28M units (devices by lots, kits, etc)  
Range 4-27M (Moistureplus Solution)
- For March 2007 – 142 Class II recalls  
35M individual units (just one month)  
Range 1-33M (Lifescan one touch test strips)



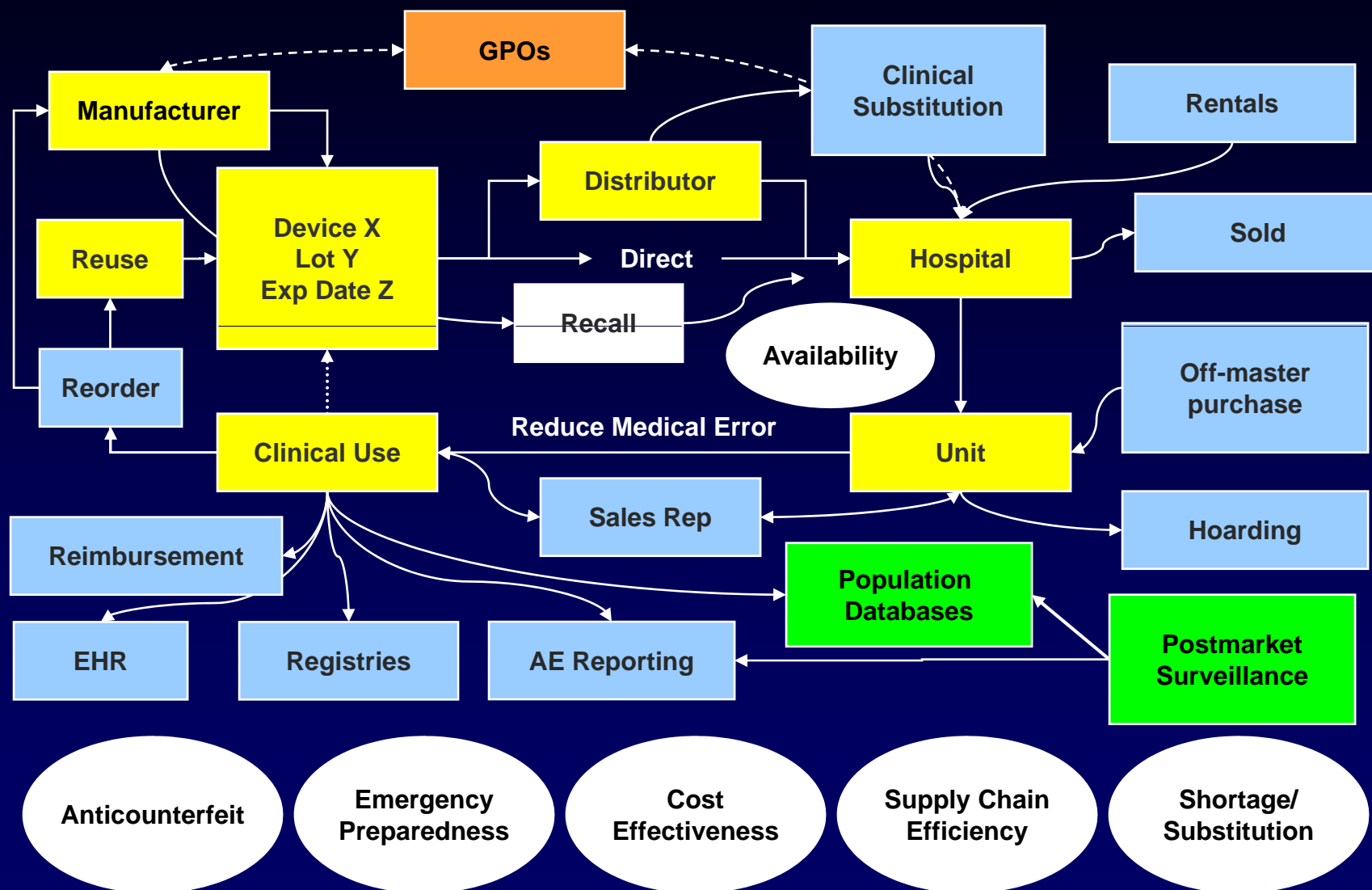
# FDA - Medical Device Identification

- Develop a system to identify medical devices which is:
  - Consistent
  - Unambiguous
  - Standardized
  - Differentiates along all identification dimensions
  - Unique at all levels of packaging
  - Harmonized internationally

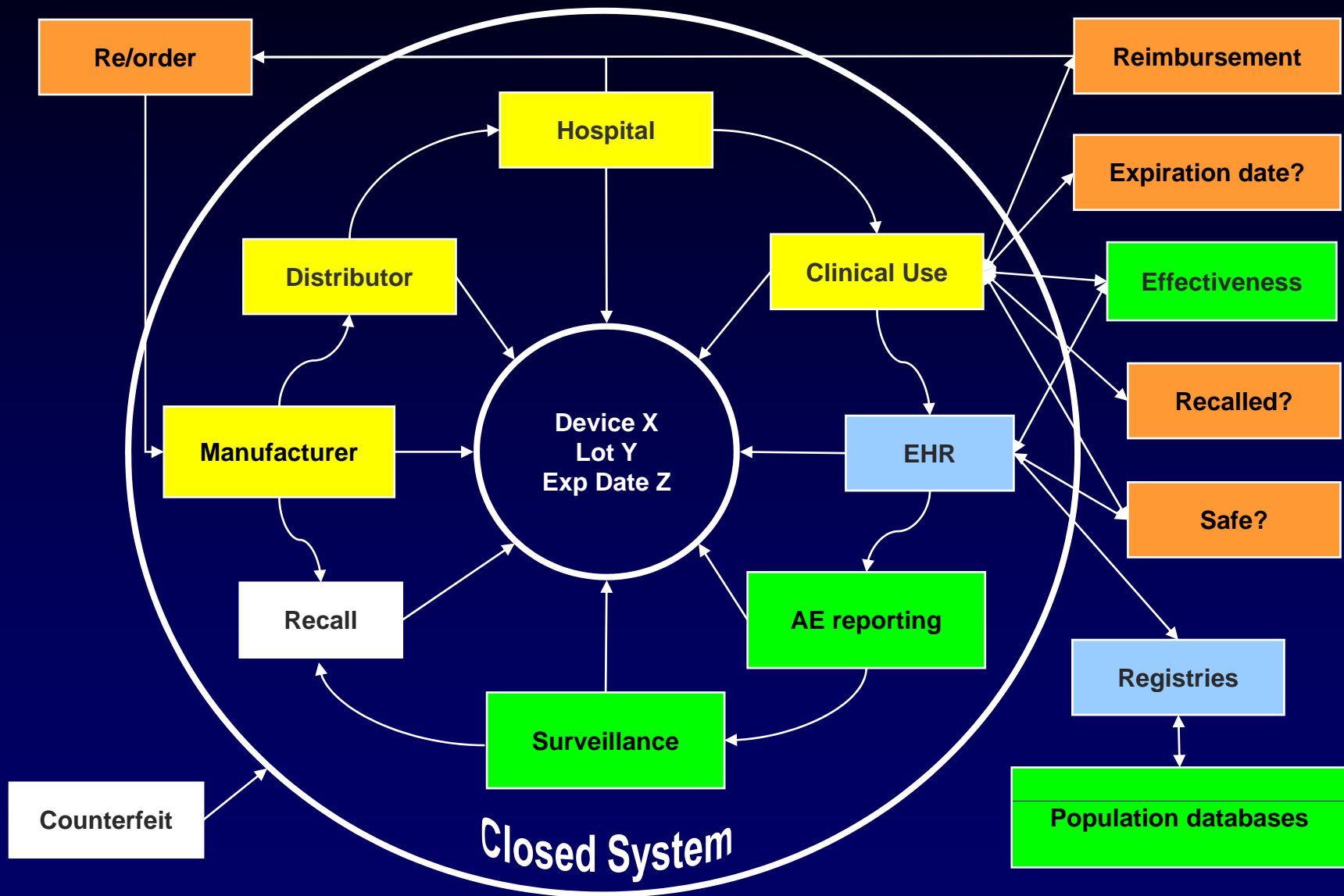
## FDA - UDI Can Improve...

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Disaster/terror preparation and shortages/substitutions
- Systems to reduce medical errors
- Assisting clinicians in identifying appropriate device
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

# Device Information Lifecycle



# Future Information Lifecycle





Unique Device Identification  
[www.fda.gov/cdrh/oct/udi/](http://www.fda.gov/cdrh/oct/udi/)  
Email: [cdruhdi@fda.hhs.gov](mailto:cdruhdi@fda.hhs.gov)

# What is GLN? Global Location Number

A globally unique 13-digit number that identifies:  
Legal entities

- Whole companies, health systems, divisions

Functional entities

- Specific department within a legal entity, (e.g., pharmacy, receiving department, etc.)

Physical locations

- Clinics, units, warehouses, loading docks, etc.

Used instead of phone numbers, store numbers,  
DUNS+4, etc.

A global standard of the GS1 System for  
collaborative commerce



# GS1 Member GLN

## 13-digit number

Components:

1. GS1 Company Prefix - Varies in length

2. Location Reference number  
Assigned by the company

3. Check Digit

- *Can also be assigned randomly by GS1 US*
- *No intelligence*
- *Maintenance*

Combined  
length is  
always 12  
digits



# GLN Registry for Healthcare<sup>®</sup> Health System Example

The screenshot displays the 'Location Maintenance' interface of the GLN Registry for Healthcare. The top navigation bar includes tabs for 'Search', 'Edit', 'New', and 'Audit'. The sidebar on the left contains the following links: 'Locations', 'Users', 'Subscriptions', 'Notifications', 'Reports', 'Exports', 'Import', 'Location Settings', 'Add New GPO', 'Help', and 'Print Screen ->'. The main content area shows a hierarchical tree view of locations, with the following entries:

- GEISINGER HEALTH SYSTEM FOUNDATION (1100002569136)
  - GEISINGER CLINIC (1100002376260)
  - GEISINGER COMMUNITY HEALTH SERVICES (1100005054301)
  - GEISINGER HEALTH PLAN (1100003274978)
    - GEISINGER HEALTH PLAN MARKETING (1100003889097)
    - GEISINGER HEALTH PLAN MOOSIC (1100002656515)
    - GEISINGER HEALTH PLAN STATE COLLEGE (1100002345242)
    - GHP MARKETING AND SALES (1100005018693)
  - GEISINGER HEALTH SYSTEM ACCOUNTS PAYABLE (1100003779374)
  - GEISINGER MEDICAL CENTER (1100004348319)
  - GEISINGER MEDICAL MANAGEMENT CORPORATION (1100002504182)
  - GEISINGER SOUTH WILKES BARRE (1100004854773)
  - GEISINGER SYSTEM SERVICES (1100004963093)
  - GEISINGER WYOMING VALLEY MEDICAL CENTER (1100005700116)
  - Geisinger Health System Foundation Affiliates (1100005947894)
- MARWORTH (1100004689528)
  - MARWORTH TREATMENT CENTER (1100004738646)

The bottom of the main content area has tabs for 'Info' and 'Hierarchy'. The sidebar also includes a 'Logged In' section showing 'As: UCC Super User' and 'At: 5/14/2009:14:39:51', along with a 'Logout' button.

# 2010 GLN Sunrise



## “Adoption of GLN in Healthcare by 2010\*”

Global Location Numbers (GLNs)\*\*

- GLNs are assigned by location owners
- GLNs are used in appropriate business transactions and processes between trading partners
- GLN hierarchy is defined and maintained by location owners
- GLN Registry for Healthcare® is used to facilitate correct location identification

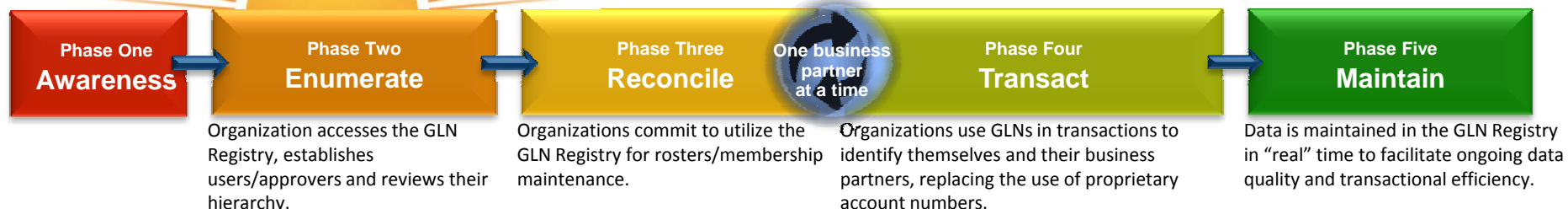
*\*December 2010*

*\*\*Unique Location Identifiers*



# 2010 GLN Sunrise

## "Adoption of GLN in Healthcare by 2010"



Provider	An organization's supply chain leaders and staff know about GLNs, their benefits, and standards in general and commit to implement.	<ul style="list-style-type: none"> <li>* Certifies accuracy of data and maintains in real time as business partners rely exclusively on the accuracy of this data.</li> <li>* Assumes responsibility for enumeration of locations to ship-to, bill to, and pay from level with GLNs.</li> </ul>	<ul style="list-style-type: none"> <li>* Provider maintains data in registry "real" time.</li> <li>* Begin to utilize GLN to identify business partners in internal systems.</li> <li>* Work with business partners to align existing account numbers to GLN.</li> </ul>	<ol style="list-style-type: none"> <li>1. Agreements between the manufacturer/distributor and GPO should have membership rosters submitted with the GLN as the identifier and the applicable demographics for their membership and that payments back to the GPO include the GLN and demographics.</li> <li>2. Agreements between the manufacturer and IDN/Single Facility should reference the customers covered using their GLN and demographics.</li> <li>3. Agreements between the manufacturer and distributor/wholesaler should detail electronic transactions. The use of 832 (Price Sales Catalog) &amp; 845 (Price Authorization) should reference GLNs.</li> <li>4. Agreements between the distributor/wholesaler and IDN/Single Facility should use GLNs. Provider agreements with their trading partners should include locations (address) listing as appropriate.</li> <li>5. Recommend GLNs replace custom identifiers with GLNs in these processes for both electronic and EDI transactions (purchase orders, Advance Ship Notice, etc.): <ul style="list-style-type: none"> <li>-850 (Purchase Order[PO])/855 (Reply to PO)/860 (PO Change Request)/856 (Advanced Ship Notice) first priority, scalable and repeatable</li> <li>-810 (Invoice) later in process.</li> </ul> </li> <li>6. Replacement of GLNs in paper transactions should follow as business partners are technically capable.</li> </ol>	<ul style="list-style-type: none"> <li>* Maintain GLN hierarchy in registry "real" time, resulting in database or record for business partners' communication.</li> <li>* Becomes final arbiter of GLN and all disputes are adjudicated via provider.</li> </ul>
	Supplier	<ul style="list-style-type: none"> <li>* Certifies accuracy of data and maintains real time.</li> <li>* Enumerates the order from and pay to locations with GLNs.</li> </ul>	<ul style="list-style-type: none"> <li>* Begin to utilize GLN to identify business partners in internal systems.</li> <li>* Work with business partners to align existing account numbers to GLN.</li> <li>* Align existing account numbers and GPO proprietary ID to GLNs, where applicable.</li> </ul>		<ul style="list-style-type: none"> <li>* Maintain info in systems utilizing GLN, ship/order/sales tracing/contracts.</li> <li>* Access registry to maintain location information and accept final judgment of provider on accuracy of GLN.</li> </ul>
	GPO	<ul style="list-style-type: none"> <li>* Initially enumerates locations at ship-to level until the provider assumes responsibility.</li> <li>* Assists provider members with education, hierarchy design and general enumeration strategy.</li> <li>* Display ship-to locations with GLNs within their roster.</li> <li>* Adjudication assistance to members, but final decision is made by provider.</li> </ul>	<ul style="list-style-type: none"> <li>* Work with business partners to align existing internal account numbers to the GLN number.</li> </ul>		<ul style="list-style-type: none"> <li>* Maintain roster membership lists using only GLN, reporting/fees done by GLN.</li> <li>* Adjudication assistance to members, but final decision is made by provider.</li> </ul>

# What is GDSN?

## Global Data Synchronization Network

### GS1 Global Registry®

The GDSN acts as a "yellow pages directory" that:

- Provides information for subscription sharing
- Enables Data Pool interoperability
- Guarantees uniqueness of the registered items and parties
- Ensures that all Data Pools in the network comply with a common basic set of validation rules that support data integrity in the system
- Holds the information about who has subscribed to trade item or party data
- Seamless integration from manufacturer to distributor to provider



# Key Elements of the GDSN

## GDSN-certified Data Pools

- Electronic catalogues of standardized item data, serving both as a source and/or recipient of master data.
- Can be run by a GS1 Member Organization, supplier, customer, exchange or service provider.





# GTINs within GDSN

To begin the data synchronization process, GTINs are provided to a GDSN-certified Data Pool.

GTINs: Used to uniquely identify products

- GDSN prevents duplicates

GTIN: “Key” in the Data Pool

- Product data attributes are linked to the GTIN

GTINs: Synchronized

- Defined once and used until changed or deleted



## 40 Global GDSN Attributes for Healthcare

Global Trade Item Number (GTIN)  
Pack Level  
Manufacturer Part Number  
Hierarchy (Parent GTIN)  
Hierarchy (Child GTIN)  
Hierarchy (Quantity of Children)  
Publisher Global Location Number (GLN)  
Target Market  
Brand Owner and GLN  
Manufacturer Name and GLN  
Functional Name  
Brand Name  
Description  
Height + Unit of Measure  
Width + Unit of Measure  
Depth + Unit of Measure  
Gross Weight + Unit of Measure  
Net Content + Unit of Measure  
Consumer Unit Y/N  
Orderable Unit Y/N

Invoice Unit Y/N  
Shipping Unit Y/N  
Base Unit Y/N  
Variable Unit Y/N  
Returnable Package Y/N  
Marked with Lot Number Y/N  
Bar code Type  
GPC code  
Optional Classification Agency  
Optional Classification Agency Value  
Start Date  
Effective Date  
Shelf Life From Production  
Shelf Life From Delivery  
Contains Blood  
Implantable  
Contents of Concern  
Reusability Types  
Brand or Generic Flag  
Does Product Contain Latex



# GLNs within GDSN

**The first step in utilizing a Global Data Synchronization Network (GDSN) Data Pool is registering your organization's GLNs**

- The GLN is required to uniquely identify your organization
- Depending on your business structure, you may have one or more GLNs registered
- The GLN identifies where information is being sent (e.g., a hospital) and who owns the information (e.g., a supplier)



# Why Are These Standards Important?

## A few examples ...

Electronic commerce, such as EDI – ensures accurate product data to be used for more types of business transactions and interoperability

Data Synchronization – healthcare needs to be able to synchronize product data – globally

Serialization – ability to know *where and when* a trade item is, based again, on a global standard

Decreasing counterfeiting of grey and black market sales – therefore improving patient safety

Contracting and compliance – sourcing product data with improved accuracy

Enables regulatory compliance with less costs and more efficiencies:

- Medical device recalls, adverse reporting, track and trace, disaster/terror preparation and device shortages, reduce medical errors, and document medical device use in patient's EHR/PHR

## And much more ...

***...but trading partners must facilitate this data!***



# The GS1 Global Registry and 27 Certified Data Pools



## Activities & Updates

- Active in GS1 US & German and other Healthcare Work Groups
- Active in the GS1 Global Healthcare Work Groups
- Actively engaged with the GDSN Global Implementation “Call To Action” project
- GHX Health ConneXion™, the GDSN certified data pool is now live
  - 3 new suppliers participating & 6 new providers
  - GHX welcomes Novation as the first GPO to join GHX Health ConneXion
- GDSN Board Membership pending with David Kerr of GHX Europe
- Initiated the GHX Industry Standards User Group in January 2009
  - Updates and working sessions on GLNs at GHX, FDA UDI Updates and more
  - Over 60 GHX members & growing – Join Us?
- Continue to work with members as requested for GS1 support
- Continue work on Content & Classification – UNSPSC and eClass
- GHX continues to support USA’s FDA Unique Device Identifiers (UDI) Initiative:
  - Working with FDA to promote more communications on the UDI and assist as requested
  - GHX engaged with the Global Harmonization Task Force for the potential “global UDI” work

# GDSN US Data Pools for Healthcare

## 1 SYNC

Todd Silberlust

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609-620-8027



## GHX

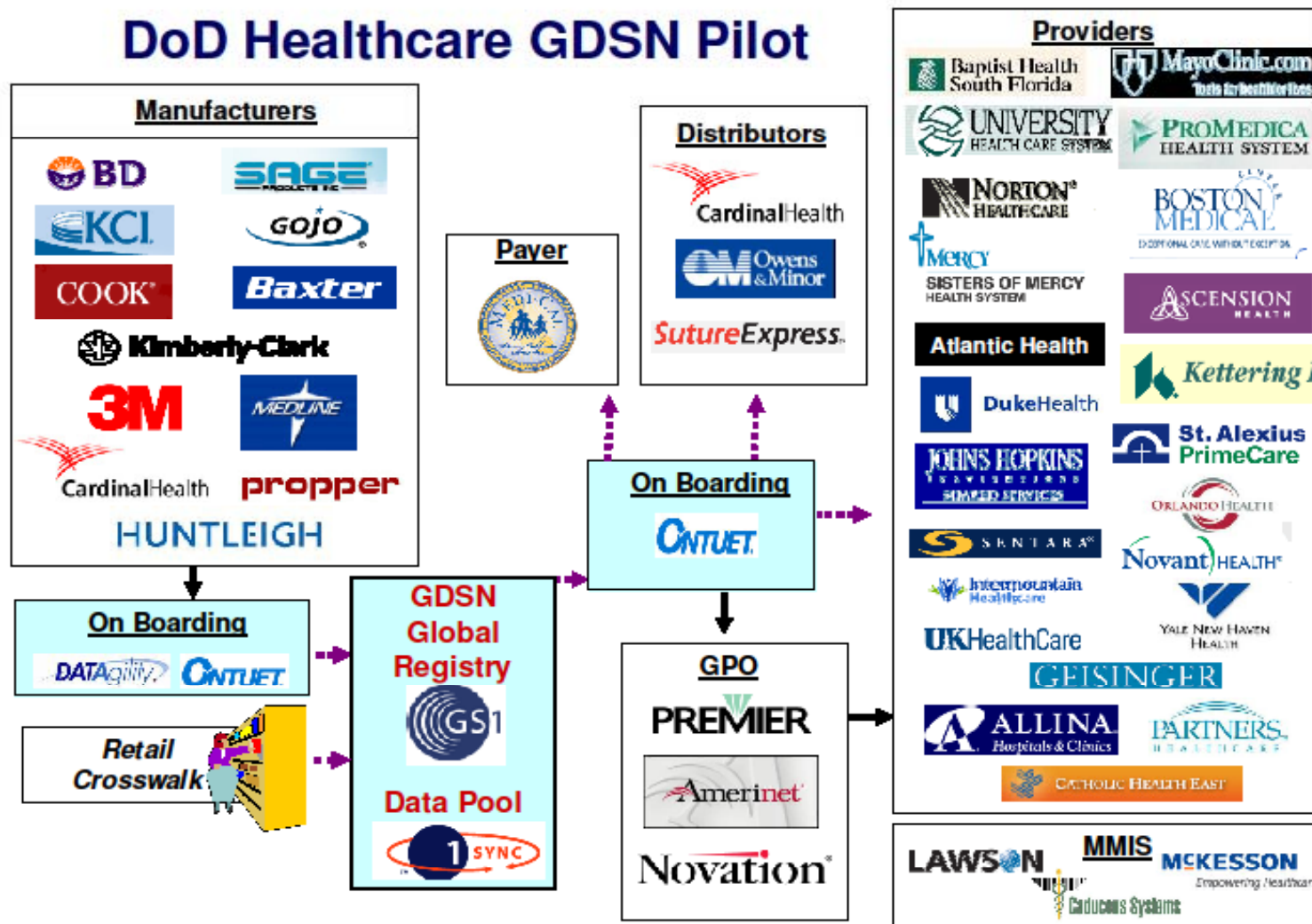
MJ Wylie

[mjwylie@ghx.com](mailto:mjwylie@ghx.com)

USA mobile 303-961-7050



## DoD Healthcare GDSN Pilot





# United Nations Standard Products & Services Code® (UNSPSC)

**An open, global, multi-industry standard used to classify products and services**

- Provides a structure or framework for product classification
- Provides a way to categorize products and services to help users organize products for catalogs, databases and listings

*Owned by: United Nations Development Programme (UNDP)*

*Managed by: GS1 US (6 years)*

**Designed to facilitate electronic commerce**

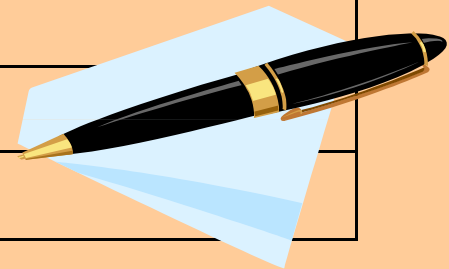
- Help streamline the procurement process
- Help analyze spending
- Help customers find products



# UNSPSC (Overview & Example)

## Using the Codeset

<i>Hierarchy</i>	<i>Category Number and Name</i>
<b>Segment</b>	<b>44 - Office Equipment and Accessories and Supplies</b>
<b>Family</b>	<b>10 - Office machines and their supplies and accessories</b>
<b>Class</b>	<b>11 - Office and desk accessories</b>
	<b>15 - Mailing supplies</b>
	<b>16 - Desk supplies</b>
	<b>17 - Writing instruments</b>
<b>Commodity</b>	<b>04 - Ball Point Pens</b>



**44101704 : Ball Point Pens**

# GS1 Healthcare US™ - Workgroups

Workgroup		Workgroup Participants
1.	Product Identification (GTIN)®	81
2.	Location Identification (GLN)	121
3.	GDSN® Implementation	95
4.	Traceability Adoption	115
5.	Application & Implementation	37



# Current Workgroup Initiatives

## Supplier Tool Kits (GTIN, GLN, GDSN) – Now Available

### Product Identification (GTIN)

- Defining 2012 GTIN Sunrise
- Scanner purchase and maintenance criteria
- Troublesome bar code procedures

### Location Identification (GLN)

- Defining 2010 GLN Sunrise
- Defining 2010 phases for implementation

### GDSN Implementation

- Defining healthcare requirements (i.e., product attributes)
- Participating in the global GDSN Implementation Initiative
- Facilitating production use of the GDSN



# Current Workgroup Initiatives

## Traceability Adoption

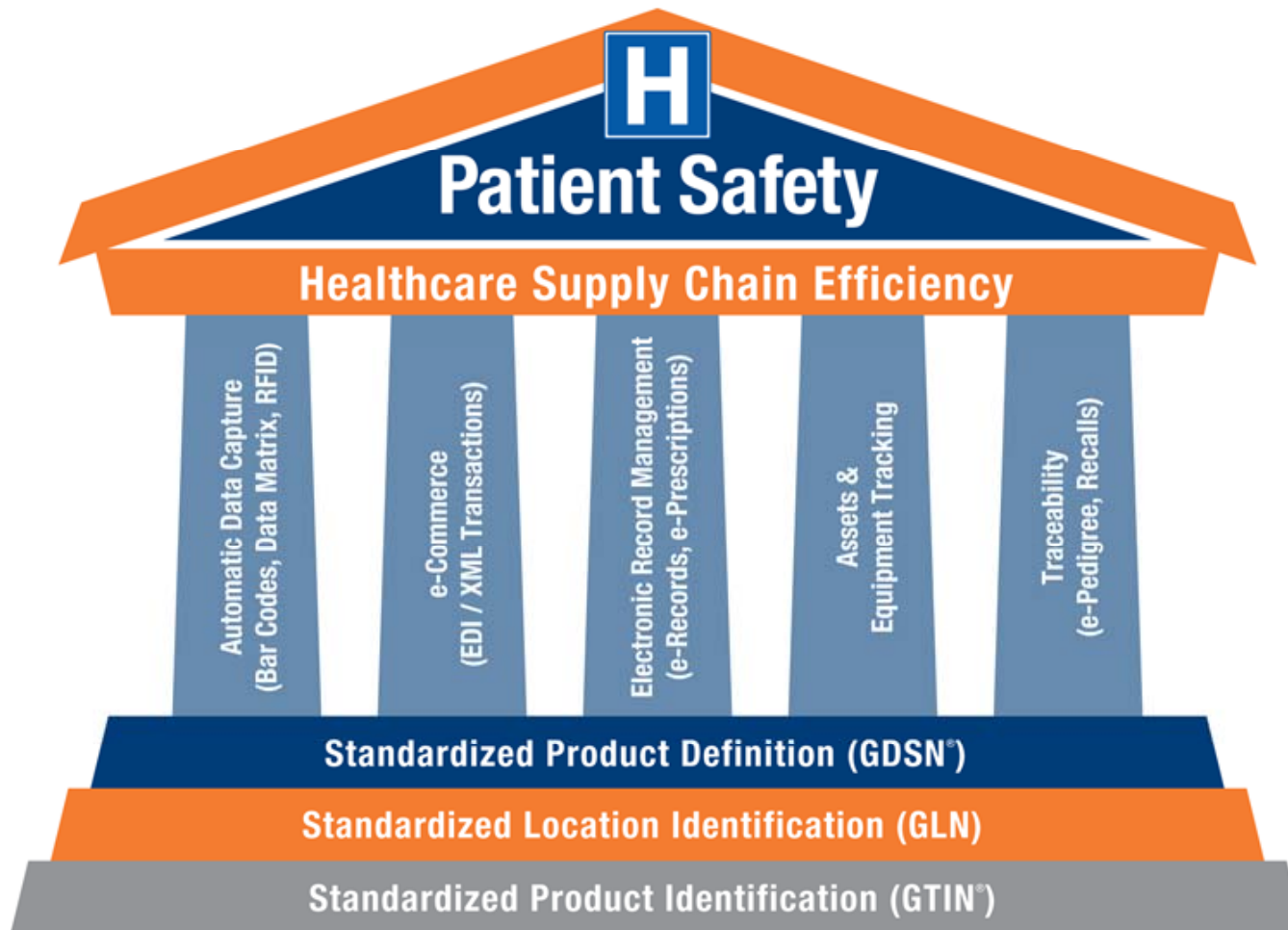
- Developing Traceability / Visibility topic papers
- Addressing RFID Security and Privacy
- Creating usage documentation for Drug Pedigree and Traceability technologies
- Developing benefits analysis of serialized products and Traceability data
- Creating education material for industry and regulators

## Application & Implementation

- Determining areas of greatest need for AIDC in hospitals
- Building an implementation guide for hospitals (GTINs, GLNs, and GDSN)
- Working with healthcare information systems providers to support the adoption of GS1 standards



## *“Building Patient Safety”*



Standardization  Interoperability



## Drive Adoption / Implementation?

- Tool Kits
- Pilots / Business cases / Training
- Solution provider outreach – identify product needs, software support, etc.
- Scorecards
- Advise U.S. regulators
- Coordinate with existing industry groups
- Implementation guidelines

**ACHIEVE REAL RESULTS!**



# Tools & Resources

## Industry Use Cases

- ***New! GLN GPO Roster Pilot Report***
- ***A GS1 Healthcare US™ Success Story:***  
Seton Family of Hospitals and BD Use GS1 Standards and Processes to Reduce EDI Errors in Pursuit of “Perfect Orders”
- **Mayo Clinic / Cardinal Health GLN Implementation White Paper**
- **Available on the GS1 Healthcare US website at [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare)**
- **Awareness Video: *Standardization...Stat***  
Developed the industry to create awareness, at all organizational levels, on the need for standards adoption and the industry-wide implementation initiative  
**Available at [www.gs1us.org/stat](http://www.gs1us.org/stat)**







# GS1 Healthcare US Upcoming Events

## ***New! GS1 Healthcare US Education Suite***

- The Basics of GS1 Standards in Healthcare
- Sunrise 101: What You Need to Know to Meet the 2010 GLN & 2012 GTIN Industry Sunrise Dates
- GLN 101 for Healthcare Location Identification
- GTIN 101 for Healthcare Product Identification
  - Sessions scheduled for Nov. 2009, Jan. & Feb. 2010
  - Register today at [www.gs1us.org/hcedu](http://www.gs1us.org/hcedu)



- Q. Are any big MMIS (Materials Manager Information System) companies engaged with the 2010-12 healthcare initiative?**
- A.** There are 22 solution providers that are members of GS1 healthcare US, including Lawson and Software who are very involved with the healthcare community on this initiative. The community is always looking for additional MMIS companies to become more involved.
- Q. Is UNSPSC® a GS1 Standard?**
- A.** No, GS1 US™ has managed the UNSPSC (United Nations Standard Products and Services Code®) for the last five years but UNSPSC is not a GS1 Standard. Since UNSPSC is widely used, GS1 Healthcare US published a Healthcare Provider Tool Kit ([www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit)) to support its use. Visit the UNSPSC website for more information ([www.unspsc.org](http://www.unspsc.org)).
- Q. Is there a “sunrise” date for UNSPSC?**
- A.** No, UNSPSC does not have a sunrise date.
- Q. Will today’s presentation be available to the public?**
- A.** Yes, today’s presentation will be available via a link on the GS1 Healthcare US website ([www.gs1us.org/healthcare](http://www.gs1us.org/healthcare)). More information regarding that link and today’s web seminar will be sent to the attendees
- Q. How does a company become involved with the healthcare initiative?**
- A.** Companies can join GS1 Healthcare US to participate in one or more workgroups for GLN (Location Identification), GTIN® (Product Identification), GDSN® Implementation, Traceability Adoption and/or Application & Implementation. In addition, membership offers the opportunity to attend GS1 Healthcare US Workgroup Forums and receive timely communications on standards initiatives. (Learn more at [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare))



**Q. How does a company migrate from HIN (Health Identification Number)?**

**A.** A company that wants to migrate from HIN, should first read the GLN Healthcare Provider Tool Kit which is available on the GS1 Healthcare US website ([www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit)), then begin attending the workgroup sessions. The GS1 US Customer Service representatives have experience in assisting these migrations and are ready to help you. (GS1 US Customer Service phone number: + 1 937.435.3870)

**Q. What are the benefits of the GLN Registry for the provider?**

**A.** The GLN Registry for Healthcare® eliminates IT crosswalks because it provides every subscriber with standardized information regarding a company's location(s). It also quickens the turnaround time for chargebacks and rebates.

**Q. Can you explain what specific GTIN attributes are?**

**A.** GTIN attributes identify product specific data and are part of the GDSN. Companies can subscribe to the GDSN through a GS1 GDSN-certified data pool.

**Q. It's relatively easy to understand how hospitals benefit from the healthcare initiative, but what's the buy-in for suppliers?**

**A.** The biggest payback in all of the industry studies is with suppliers. Both hospitals and suppliers benefit from the healthcare initiative through rationalization of IT services; prompt resolution of customer rebate, billing, and shipping discrepancies.

**Q. Is the 2010 GLN sunrise date mandatory?**

**A.** No, but the healthcare community is looking for compliance by 2010. Keep in mind that this initiative began in the community with Mayo, Premier, and Amerinet to name a few leaders; it did not originate from GS1 US.



**Q: Explain the importance of FDA Unique Device Identification (UDI) Workshop?**

**A:** Please review the 2004 Guidance on Pharmaceuticals, which can be found on the GS1 Healthcare US Online Document Library under “Product Identification”. It is important for providers, manufacturers, and distributors to forward their questions to the FDA. The FDA wants to hear from industry participants regarding package levels. For example, should every needle be tracked or should needles be tracked at package level?

**Q: Will the FDA UDI effect global companies?**

**A:** No, the FDA UDI initiative will only affect U.S. companies.

**Q: As a distributor working with a GPO, will distributors need GLNs?**

**A:** Yes, part of why the GS1 Healthcare US Supplier Tool Kit is being developed. Please download the GS1 Healthcare US Provider Tool Kit as much of it will apply to this question. ([www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit))

**Q: Are GLNs and GTINs one in the same?**

**A:** No. GLNs are used to uniquely identify locations and GTINs are used to uniquely identify products and services.

**Q: I received a CD from the AHRMM Conference last year. Is the presentation today, the same as what's on the CD?**

**A:** No, the CD contains much more in-depth information.

**Q: Will there be a process to combine all solution provider systems?**

**A:** GS1 Healthcare US is working with solution providers to urge them to get involved so they understand what is needed for systems implementation of GS1 standards.



**Q: Is a product's "expiration date" and "serial number" included in the GTIN attributes?**

**A:** Beyond the *product description attributes* defined by the manufacturer (e.g., size; color; brand information; etc.), there may be certain *item specific attributes* that manufacturers or supply chain partners want on products themselves to provide item specific information *at the point where the bar code is scanned* (e.g., expiration date; lot number; batch number; etc.). In order to facilitate that, the GS1 System provides "Application Identifiers" (AIs) for encoding item specific attributes directly into GS1 bar codes and GS1 RFID tags [known as GS1 Electronic Product Code (EPC) Tags].

**Q: Does GS1 maintain a manufacturer's item master, or should each company plan to be responsible for maintaining their own data?**

**A:** Each manufacturer (brand owner) is responsible for assigning their GTINS and maintaining their own data. In order to create a GTIN, a manufacturer will need to first obtain a GS1 Company Prefix from GS1 US. The GS1 Company Prefix is a globally unique number licensed to your company/organization by GS1 US, and the foundation to create the identification numbers of the GS1 System. The GS1 Company Prefix is what makes the identification numbers of the GS1 System unique. When a manufacturer creates a GTIN, they also define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). The GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. For more information on obtaining a GS1 Company Prefix, please call GS1 US at +1 937.435.3800. For more information on the GDSN see the Healthcare Provider GDSN Tool Kit at ([www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit)).



**Q: Regarding the 2012 GTIN Sunrise definitions shown in the presentation; will there be metrics to follow the progress of this initiative through 2012?**

**A:** The GS1 Healthcare US Product Identification (GTIN) workgroup is currently working on metrics to monitor industry progress on meeting the 2012 GTIN Sunrise goals.

**Q: Please provide an update on efforts for standardization within the FDA that calls for a serialized Nation Drug Code (sNDC).**

**A:** The National Drug Code (NDC) is used to identify pharmaceutical products and the National Health Related Item Code (NHRIC) is used to identify medical/surgical products pursuant to FDA regulations. For over thirty-five years, GS1 has supported manufacturers of healthcare products in integrating these regulatory identifiers into their GTINs. Integration of NDC/NHRIC into GTINs is optional, and not all pharmaceutical or medical surgical companies integrate their NDCs/NHRICs into their GTINs. Refer to the Healthcare Provider GTIN Tool Kit to see how this works ([www.gs1us.org/hcptoolkit](http://www.gs1us.org/hcptoolkit)) The draft FDA *Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages* states that use of sNDC is compatible with, and may be presented within, a serialized Global Trade Item Number (serialized GTIN or sGTIN). (The draft guidance can be found at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm>)



**Q: Where can I find a full list of the GDSN attributes for healthcare products?**

**A:** A full list of attributes is provided in this presentation. The *GTIN Attributes for Healthcare Products - Interactive Spreadsheet* is also available on the GS1 Healthcare US website (See *Additional Resources* at <http://www.gs1us.org/Default.aspx?tabid=210>).

**Q: Will the GDSN product attributes include items such as hazard codes?**

**A:** Not at this time. Currently there are 40 attributes that have been reviewed and approved by U.S. participants as the foundation for GDSN adoption in U.S. healthcare. The Global Standards Management Process (GSMP) Healthcare GDSN Extension work group is working on further enhancements to GDSN attributes to support healthcare specific data requirements. While the global community refines these enhancements to support additional product data needs, users already implementing GDSN (or planning to) can continue as planned. There is no need to delay these plans or to wait until the additional requirements are defined. The healthcare community can recommend additional/optional attributes to meet their needs through the GSMP (<http://www.gs1.org/gsmg/overview>) or raise requests through the GS1 Healthcare US GDSN Implementation Workgroup (email [GS1HealthcareUS@gs1us.org](mailto:GS1HealthcareUS@gs1us.org)).

**Q: How can I join and become an active member of GS1 Healthcare US?**

**A:** Companies can join GS1 Healthcare US to participate in one or more workgroups for GLN (Location Identification), GTIN® (Product Identification), GDSN® Implementation, Traceability Adoption and/or Application & Implementation. In addition, membership offers the opportunity to attend GS1 Healthcare US Workgroup Forums and receive timely communications on standards initiatives. (The member application is available at [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare)) or contact GS1 Healthcare US by email at [GS1HealthcareUS@gs1us.org](mailto:GS1HealthcareUS@gs1us.org).

**Q: Where can I find a list of all the manufacturers who have registered GTINs in the GDSN?**

**A:** A list of all companies participating in the GDSN can be found on the GS1 website at [www.gs1.org/gdsn/statistics](http://www.gs1.org/gdsn/statistics)

**Q: Are there guidelines for bedside scanning?**

**A:** There are two new guidelines from GS1 Healthcare US that will be available shortly to assist in this area:

- *Simplified Guide for U.S. Healthcare Bar Code Scanner Acquisition Criteria*
- *Procedure for Responding to Troublesome Bar Codes*

**Q: What is the fee to join GS1 Healthcare US?**

**A:** The membership fee varies by healthcare provider, GPO, distributor, manufacturer or solution provider. The fees are listed on the membership application available on the GS1 Healthcare US website. Visit [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare) and click on "Join Today" in the left links box.





**Q: Does the GTIN have embedded intelligence? Can I tell who the manufacturer is by looking at the GTIN?**

**A:** The GTIN has no logic or intelligence embedded by design. It is a pointer to a data base where the information resides. Because of the variable length company prefix, it can not be parsed to determine the manufacturer.

**Q: What type of hand-held surgical instruments might fall under this system?**

**A:** GTINs already identify many hand held surgical instruments.

**Q: Are the MMIS software providers interfacing all of this (GS1System) to their respective systems?**

**A:** A recent survey of the top MMIS vendors demonstrated that they aware of the GS1 standard initiatives and are working to embed the standards in their software . The timelines and degree of implementation varies by vendor .





Improving Patient Safety and Supply Chain  
Efficiency with Data Standards: The Basics of  
GS1 Standards in Healthcare

## **Questions?**

**Feel free to email your questions to:  
[GS1HealthcareUS@gs1us.org](mailto:GS1HealthcareUS@gs1us.org)**